No. 16-1140

IN THE

Supreme Court of the United States

NATIONAL INSTITUTE OF FAMILY AND LIFE ADVOCATES, D/B/A NIFLA, ET AL.,

Petitioners,

v.

XAVIER BECERRA, ATTORNEY GENERAL, ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

Amici Curiae Brief of the American Academy of Pediatrics, California, the American College of Obstetricians and Gynecologists, the American Medical Women's Association, the American Nurses Association\California, the American Society for Reproductive Medicine, the Association of Reproductive Health Professionals, the California Medical Association, the National Abortion Federation, the National Perinatal Association, and the Society for Adolescent Health and Medicine in Support of Respondents

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CONSENT TO FILE AS *AMICI CURIAE*

This brief is filed with the consent of the parties pursuant to Rule 37(3)(a) of the Rules of the Supreme Court of the United States.

INTEREST OF *AMICI CURIAE*[1]

The American Academy of Pediatrics, California, the American College of Obstetricians and Gynecologists, the American Medical Women's Association, the American Nurses Association\California, the American Society for Reproductive Medicine, the Association of Reproductive Health Professionals, the California Medical Association, the National Abortion Federation, the National Perinatal Association, and the Society for Adolescent Health and Medicine (collectively "*Amici*") respectfully submit this brief *Amici Curiae* in support of Respondents.

Amici are organizations dedicated to health care, research, and health policy. These organizations are committed to improving women's health and preserving women's access to comprehensive health care. *Amici* respectfully submit this brief to share their collective learning

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[1] Pursuant to Rule 37.6 of the Rules of the Supreme Court of the United States, counsel for *Amici Curiae* represent that no counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity other than *Amici Curiae* and their counsel made such a monetary contribution.

about the likely negative impact that reversal of the decision below would have on women's health. *Amici* are as follows:

- The **American Academy of Pediatrics, California** ("AAP-CA") is a legally incorporated nonprofit member association, comprised of the four AAP California chapters statewide representing approximately 5,000 board-certified primary care and subspecialty pediatricians. The mission of the AAP-CA is to promote the health and well-being of all children and youth living in California. This includes support for access to medically accurate information regarding reproductive health care services for young women.

- The **American College of Obstetricians and Gynecologists** ("ACOG") is a non-profit, voluntary membership organization. With more than 58,000 members, ACOG is the premier professional membership organization of obstetricians and gynecologists and others dedicated to the improvement of women's health. ACOG promotes the advancement of women's health care through continuing medical education, practice, research, and advocacy.

- The **American Medical Women's Association** ("AMWA") is an organization of women physicians, medical students and others dedicated to serving as the unique voice for women's health and the advancement of women in medicine. AMWA does this by providing and developing leadership,

advocacy, education, expertise, and mentoring. AMWA is an active participant in setting health care policy to promote women's health issues.

- The **American Nurses Association\California** ("ANA\C") represents all registered nurses in the state of California, without regard to specialty or practice setting. The American Nurses Association ("ANA") and its state chapters advance the nursing profession by fostering high standards of nursing practice, promoting the rights of nurses in the workplace, projecting a positive and realistic view of nursing, and by lobbying the legislature and regulatory agencies on health care issues affecting nurses and the public. ANA\C is aligned with ANA policy in advocating for access to safe, timely, and quality care for all populations. ANA is a leader in promoting policies on reproductive and human rights, social justice, and ethical standards.

- The **American Society for Reproductive Medicine** ("ASRM") is a non-profit multidisciplinary organization dedicated to the advancement of the science and practice of reproductive medicine. ASRM accomplishes this mission through the pursuit of excellence in education and research and through advocacy on behalf of patients, physicians, and affiliated health care providers.

- The **Association of Reproductive Health Professionals** ("ARHP") brings together health care professionals across disciplines and specialties for evidence-based training and network building. ARHP delivers on its educational mission by translating good science into practice through producing accredited, peer-reviewed programs.

- The **California Medical Association** ("CMA") is a non-profit, incorporated professional association for physicians with approximately 43,000 members throughout the state of California. For more than 150 years, CMA has promoted the science and art of medicine, the care and well-being of patients, the protection of public health, and the betterment of the medical profession. CMA's physician members practice medicine in all specialties and settings, including providing reproductive health services.

- The **National Abortion Federation** ("NAF") is the professional association of abortion providers. NAF's mission is to ensure safe, legal, and accessible abortion care, which promotes health and justice for women. NAF's members include private and non-profit clinics, Planned Parenthood affiliates, women's health centers, physicians' offices, and hospitals. NAF is the leading organization offering accredited continuing medical education to health care professionals in all aspects of abortion care, and NAF

member providers adhere to NAF's evidence-based *Clinical Policy Guidelines*, which set the standards for quality abortion care.

- The **National Perinatal Association** ("NPA") is an interdisciplinary organization of professionals, parents, and advocates that is the leading voice in perinatal care in the United States. NPA educates, advocates, and integrates all voices with equality and respect to support pregnant women, infants, and their families and the professionals who care for them. NPA works to create positive change in perinatal care by partnering with health care, government, and nonprofit organizations.

- The **Society for Adolescent Health and Medicine** is a multidisciplinary organization committed to improving the physical and psychosocial health and well-being of all adolescents and young adults through advocacy, clinical care, health promotion, health service delivery, professional development and research.

SUMMARY OF ARGUMENT

The Ninth Circuit Court of Appeals below upheld California's Reproductive FACT (Freedom, Accountability, Comprehensive Care, and Transparency) Act, Cal. Health and Safety Code 123470 *et seq.*; Assemb. B. No. 775,2015-2016 Reg. Sess. (Cal. 2015) (the "FACT Act"). The FACT Act (1) requires licensed medical facilities that provide pregnancy-related services to notify women of the availability of free or low-cost access to comprehensive family planning services, prenatal care, and abortion to eligible women, and (2) requires facilities that offer pregnancy-related services but are not licensed and do not have a licensed medical provider (*i.e.*, a licensed health professional regulated under California statutes) on staff to inform women of these facts. An affirmance of the decision of the court below sustaining the constitutionality of the FACT Act would have a markedly positive effect on women's and children's health and well-being by preventing unnecessary delay in women's ability to access prenatal care, contraceptive services, and abortion services and ensuring that women are well-informed about the nature of the services offered and the credentials of the individuals and facilities offering those services.

Women's pregnancy-related health care services are highly time-sensitive, and unnecessary delay can pose significant risks to maternal and fetal health. Accordingly, requiring licensed medical facilities to inform women of the availability of free or low-cost care reduces certain avoidable risks associated with delayed care and thereby promotes

health. This is particularly true if the facility does not itself offer the comprehensive family planning services, prenatal care, or abortion that is being sought, in which case a woman must seek care elsewhere.

In addition, requiring unlicensed medical facilities to inform women that there are no licensed medical providers on staff serves two important public health goals: (1) it allows women to make more fully informed decisions about the pregnancy-related services that they receive; and (2) it prevents unlicensed facilities from misleading women into believing that the services being offered are medically necessary or beneficial.

As leading medical societies, *Amici* are profoundly interested in policies that allow women to obtain desired medical services as quickly and safely as possible. An affirmance of the decision below will help advance those policies and thus further the health of women and developing fetuses.

ARGUMENT

I. Women Should Be Informed About State-Funded Prenatal Care, Family Planning And Abortion Services

At issue in this case are efforts by the State of California to ensure that patients receive accurate information about the availability and accessibility of comprehensive reproductive health services in the State. To facilitate this goal, the FACT Act requires licensed medical facilities that provide reproductive

health services to inform patients of the availability of low-cost or free family planning services, prenatal care, and abortion. Cal. Health & Safety Code § 123472(a)(1). In doing so, the FACT Act ensures that women "quickly obtain the information and services they need to make and implement timely reproductive decisions." Assemb. B. No. 775, § 1(d), 2015-2016 Reg. Sess. (Cal. 2015). As discussed below, delay in reproductive-related decisions can result in serious negative health outcomes for women, developing fetuses and infants.

A. Delayed or Inadequate Prenatal Care Poses Risks to Maternal and Fetal Health

Prenatal (or "antenatal") care for pregnant women is a crucial aspect of women's health care and is critical for ensuring the health of pregnant women and developing fetuses throughout pregnancy. Prenatal care allows a health care provider to (1) identify and assess health risks to the pregnant woman and developing fetus, (2) prevent and manage pregnancy-related health conditions, pregnancy-related diseases, and concurrent diseases of the pregnant woman and developing fetus that could impact the health of either, and (3) provide education for the pregnant woman so that she may better care for her own health and the health of the fetus. World Health Org., *WHO Recommendations on Antenatal Care for a Positive Pregnancy Experience* 1 (2016). These three goals of prenatal care are necessary to reduce risks associated with pregnancy and to

improve health outcomes for pregnant women and developing fetuses throughout pregnancy and childbirth.

1. Delayed or Inadequate Prenatal Care Increases Health Risks for Pregnant Women

Delays in obtaining accurate medical counseling and prenatal care poses risks for pregnant women. For some women, the state of pregnancy itself poses significant health risks. These risks may be even more acute for women with certain preexisting conditions. Proper prenatal care allows physicians and other qualified health professionals to assess and mitigate these risks. Pregnant women are at risk of deep venous thromboses (DVTs, or blood clots) because pregnancy results in increased vein pressure and a hypercoagulable state. This is a serious condition that can lead to pulmonary embolism or even death. *Deep Vein Thrombosis*, Mayo Clinic, http://www.mayoclinic.org/diseases-conditions/deep-vein-thrombosis/basics/definition/con-20031922; *see also* Am. Coll. of Obstetricians & Gynecologists, *Practice Bulletin No. 123: Thromboembolism in Pregnancy*, 123 Obstetrics & Gynecology 718, 718 (2011) [hereinafter *ACOG Practice Bulletin No. 123*]. Early detection allows women with preexisting clotting disorders to manage their pregnancies with the use of blood-thinning medication. *ACOG Practice Bulletin No. 123*, *supra*, at 720-21.

Other conditions may not be related to a woman's preexisting condition but may manifest during pregnancy. Such pregnancy-related risks to women include gestational diabetes, which affects approximately 6% of pregnant women and requires careful blood glucose monitoring, and hypertension disorders, which affect approximately 5-10% of pregnant women. *See* Am. Coll. of Obstetricians & Gynecologists, *Practice Bulletin No. 190: Gestational Diabetes Mellitus*, 131 Obstetrics & Gynecology e49, e49 (2018) [hereinafter *ACOG Practice Bulletin No. 190*] ("7% of pregnancies were complicated by any type of diabetes and . . . approximately 86% of these cases represented women with [gestational diabetes]."); Am. Coll. of Obstetricians & Gynecologists, *Committee Opinion No. 638: First-Trimester Assessment for Early-Onset Preeclampsia*, 126 Obstetrics & Gynecology e25, e25 at 1 (2015) ("Hypertensive disorders with adverse sequelae (including preterm birth, maternal morbidity and mortality, and long-term risk of maternal cardiovascular disease) complicate 5-10% of pregnancies."). Hypertension-related disorders such as preeclampsia are particularly dangerous—they account for "approximately a quarter of maternal deaths and near misses." World Health Org., *supra*, at 40. Timely and quality prenatal care is therefore necessary to diagnose and treat these conditions when they occur.

Additionally, some pregnancies develop abnormally and pose serious maternal health risks that need to be treated as soon as possible. For example, ectopic pregnancy, in which the pregnancy develops outside the uterus, can result in rupture of

the fallopian tubes and life-threatening bleeding if it is allowed to continue. Ectopic pregnancy occurs in approximately 2% of all pregnancies, and mortality from ectopic pregnancy is usually due to the failure to seek or receive timely medical care. *See* Am. Coll. of Obstetricians & Gynecologists, *Practice Bulletin No. 193: Tubal Ectopic Pregnancy*, 131 Obstetrics & Gynecology e91, e91 (2018). Separately, molar pregnancies, in which an abnormal pregnancy develops into a tumor, can lead to a potentially deadly cancer if not detected and treated. See *Molar Pregnancy*, Mayo Clinic, https://www.mayoclinic.org/diseases-conditions/molar-pregnancy/symptoms-causes/syc-20375175.

In addition to the management of medical conditions during pregnancy like those described above, prenatal care provides opportunities for health care professionals to screen for other related issues, such as maternal substance use, domestic violence, perinatal depression, and HIV and other sexually transmitted infections ("STIs"). *See* World Health Org., *supra*, at xi-xiv; Am. Coll. of Obstetricians & Gynecologists, *Committee Opinion No. 630: Screening for Perinatal Depression*, 125 Obstetrics & Gynecology 1268, 1268 (2015). Ensuring that women are informed of the availability of prenatal care by qualified and licensed medical providers encourages use of those services so that these conditions can be diagnosed and, if necessary, treated in a timely manner, reducing avoidable health risks posed by delay.

2. *Delayed or Inadequate Prenatal Care Increases Health Risks for Developing Fetuses and Infants*

Delayed or inadequate prenatal care is associated with negative health outcomes in developing fetuses, including premature birth, stillbirth, early neonatal death (death of a newborn within 7 days of birth), late neonatal death (death of a newborn between 7 and 27 days after birth), and infant death (any death within 356 days of birth) relative to the developing fetuses and children of women who receive adequate prenatal care. Sarah Partridge et al., *Inadequate Prenatal Care Utilization and Risks of Infant Mortality and Poor Birth Outcome: A Retrospective Analysis of 28,729,765 U.S. Deliveries Over 8 Years*, 29 Am. J. of Perinatology 787, 787 (2012). Timely prenatal care can ensure that women take necessary preventative measures for the sake of fetal health. These measures include, but are not limited to, (1) daily iron and folic acid supplements; (2) screening for asymptomatic bacteriuria (bacteria present in urine without any other symptoms), tobacco use, and HIV and other STIs; and (3) other preventative measures such as tetanus, pertussis, and influenza vaccination, all of which may reduce the risk of negative fetal health outcomes, including death. World Health Org., *supra*, at xi-xiv.

Delay in accessing and receiving prenatal care may also delay critical screenings that are needed to detect fetal health issues and initiate treatment earlier in pregnancy. For example, prenatal care often includes screening for fetal congenital heart

impairments. Rebecca F. Liberman et al., *Delayed Diagnosis of Critical Congenital Heart Defects: Trends and Associated Factors*, 134 Pediatrics e373, e375 (2014). Delayed diagnosis of fetal congenital heart impairments is "associated with serious complications, including seizure, cardiac arrest, and death" of a developing fetus or newborn. *Id.* at e374. Without timely access to prenatal care, women whose fetuses develop congenital heart impairments face delayed diagnosis, fewer potential options for treatment, and delayed treatment of the impairments, resulting in increased risk of serious fetal and infant health outcomes.

Delay in prenatal care can also result in increased risks of STI-related complications, such as mother-to-infant transmission of STIs like HIV or poor health outcomes for developing fetuses, including fetal loss or premature birth. Florence M. Momplaisir et al., *Time of HIV Diagnosis and Engagement in Prenatal Care Impact Virologic Outcomes of Pregnant Women with HIV*, 10 PLoS ONE e0132262 (2015), *available at* http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0132262; Kristina Adachi et al., *Chlamydia and Gonorrhea in HIV-Infected Pregnant Women and Infant HIV Transmission*, 42 Sexually Transmitted Diseases 554, 555 (2015). Timely detection and treatment of STIs is important not only for maternal health, but also for fetal and infant health. For example, without medical intervention, there is a substantial likelihood that an HIV-positive pregnant woman will transmit HIV to her fetus either during pregnancy or during childbirth—a likelihood that is dramatically reduced when the pregnant woman

receives treatment for her HIV infection at an early stage in her pregnancy. Momplaisir et al., *supra*, at 2.

Pregnant women with other untreated STIs such as chlamydia and gonorrhea also face potential pregnancy complications including "fetal loss, premature rupture of membranes, and preterm labor and delivery." Adachi et al., *supra*, at 555. These infections, if untreated, can cause conjunctivitis (eye infections), blindness, permanent brain damage, chronic hepatitis B, and pneumonia in infants. *Id.* Moreover, when chlamydia infections are present but untreated in HIV-positive pregnant women, they lead to an increased risk of mother-to-infant transmission of HIV. *Id.* at 563.[2]

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[2] Prenatal care also may include screening for the hepatitis B virus ("HBV") and the herpes simplex virus ("HSV"). If a pregnant woman tests positive for HBV, her baby should receive hepatitis B immune globulin and the HBV vaccine in the first twelve hours after birth. Am. Coll. of Obstetricians & Gynecologists, *Practice Bulletin No. 86: Viral Hepatitis in Pregnancy*, 110 Obstetrics & Gynecology 941, 949 (2007); Am. Coll. of Obstetricians & Gynecologists, *Practice Bulletin No. 82: Management of Herpes in Pregnancy*, 109 Obstetrics & Gynecology 1489, 1494 (2007). If prenatal screening shows that a pregnant woman tests positive for HSV, a cesarean birth may be recommended to prevent neonatal HSV infections, which, if untreated, have only a 40 percent survival rate. Lawrence Corey & Anna Wald, *Maternal and Neonatal Herpes Simplex Virus Infections*, 361 New Eng. J. of Med. 1376, 1376 (2009). Detection of maternal HBV and HSV, and thus prevention or treatment of neonatal HBV and HSV, is less likely, however, for women who do not receive prenatal care.

B. Delay in Obtaining an Abortion Poses Health Risks to Pregnant Women

Delay in obtaining an abortion creates health risks for pregnant women seeking abortions. The risks come in two distinct forms: (1) inherent risks of remaining pregnant under certain circumstances, and (2) increased risks posed by an abortion performed later than necessary.

There are myriad barriers that delay women from accessing abortion. *See* Am. Coll. of Obstetricians & Gynecologists, *Committee Opinion No. 613: Increasing Access to Abortion*, 124 Obstetrics & Gynecology 1060, 1061-64 (2014) [hereinafter *ACOG Committee Opinion No. 613*] (describing barriers to abortion access including, but not limited to, legal restrictions on abortion providers, funding restrictions, a lack of abortion providers, and stigma and violence). Some of these barriers are logistic, such as receiving inappropriate or delayed referrals, and the need to raise money to cover procedure and travel costs. *See* Am. Coll. of Obstetricians & Gynecologists, *Practice Bulletin No. 135: Second-Trimester Abortion*, 121 Obstetrics & Gynecology 1394, 1394 (2013); Eleanor A. Drey et al., *Risk Factors Associated with Presenting for Abortion in the Second* Trimester 107 Obstetrics & Gynecology 1 (2006); *ACOG Committee Opinion No. 613, supra*, at 1062 ("[F]unding restrictions impede access to safe abortion care and, in some cases, function as a de facto abortion ban."); Deborah Karasek et al., *Abortion Patients' Experience and Perceptions of Waiting Periods: Survey Evidence Before Arizona's Two Visit 24-Hour Mandatory Waiting Period Law*,

26 Women's Health Issues 63 (2016) (finding that 39% of women studied had to delay abortion due to cost).[3] The FACT Act requirement that licensed facilities inform women of the availability of free or reduced-cost abortion services addresses a major cause of delayed access to abortion.

1. The Extra Time During Which a Woman Who Has Decided to Have an Abortion Remains Pregnant Poses Health Risks

Pregnancy itself poses health risks for women, including women who have pregnancy complications or concomitant health conditions. *See supra* Section I(A)(1). Thus, a woman who has decided to obtain an abortion but remains pregnant because of delay, whether as a result of cost, misinformation, or otherwise, is exposed to preventable health risks associated with her continued pregnancy. In some cases, remaining pregnant may seriously jeopardize a woman's health.

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[3] In one study, 36.5% of women in their first trimester of pregnancy cited the cost of an abortion as a reason for delay. Ushma D. Upadhyay et al., *Denial of Abortion Because of Provider Gestational Age Limits in the United States*, 104 Pub. Health 1687, 1687 (2014) [hereinafter Upadhyay et al., *Denial*]; *see also* Marshall H. Medoff, *Race, Restrictive State Abortion Laws and Abortion Demand*, 41 Rev. Black Pol. Econ. 225, 238 (2014) ("A [state] Medicaid funding restriction reduces the abortion rate of white women by 2.0%, black women by 4.1% and Hispanic women by 10.6%.").

Women who have decided to have an abortion are unlikely to seek prenatal care. *See* Susan Hatters Friedman et al., *Characteristics of Women Who Do Not Seek Prenatal Care and Implications for Prevention*, 38 J. of Obstetric, Gynecologic & Neonatal Nursing 174, 179 (2009) (finding that "failed plans to procure abortions" is one reason women do not obtain prenatal care). Among those women, those who have preexisting conditions that increase the health risks posed by pregnancy are thus less likely to obtain the care that they require, especially if they are not aware of the preexisting condition. For example, pregnant women with preexisting clotting disorders who are unaware of this disorder may develop DVTs, *see supra* Section I(A)(1), but may not receive care that would alert them of the risk—or identify and treat the DVTs—if they are seeking abortions.[4] The additional time that these women are pregnant is thus time during which they can suffer significant health problems that could have been avoided had they received access to appropriate medical services, including timely abortion care.

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[4] Similarly, women with chronic hypertension or preexisting diabetes may experience an exacerbation of their condition at any stage of pregnancy that increases the need for treatment. *See generally* Nat'l Collaborating Ctr. for Women's & Children's Health, *Hypertension in Pregnancy: The Management of Hypertensive Disorders During Pregnancy* 61–75 (2011), *available at* https://www.ncbi.nlm.nih.gov/books/NBK62651/; John L. Kitzmiller et al., *Managing Preexisting Diabetes for Pregnancy*, 31 Diabetes Care 1060, 1061 (2008); *A Healthy Pregnancy for Women with Diabetes*, Am. Coll. of Obstetricians & Gynecologists, https://www.acog.org/Patients/FAQs/A-Healthy-Pregnancy-for-Women-with-Diabetes.

The probability of a pregnancy-related complication that threatens maternal health—and the number of possible complications—increases as the pregnancy progresses. Gestational diabetes, for example, is generally not a concern before 24 weeks of pregnancy. *See ACOG Practice Bulletin No. 190, supra*, at e50. Similarly, pregnant women who develop preeclampsia typically develop the condition after 20 weeks, with only rare occurrences of preeclampsia before then. *See Preeclampsia and High Blood Pressure During Pregnancy*, Am. Coll. of Obstetricians & Gynecologists, https://www.acog.org/Patients/FAQs/Preeclampsia-and-High-Blood-Pressure-During-Pregnancy.

Other life-threatening pregnancy-related conditions that pregnant women can develop include ectopic and molar pregnancies, which must be treated immediately. *See supra* Section I(A)(1). Licensed medical professionals providing abortion services have the qualifications and training to diagnose ectopic and molar pregnancies and treat or appropriately refer a patient for treatment of these conditions. Women with ectopic and molar pregnancies who experience a delay in obtaining abortion services, however, remain at increased, and indeed life-threatening, risk longer than necessary. The risks of pregnancy are serious, and women who do not want to be pregnant should not be subjected to those risks.

2. Health Risks Associated with Abortion Increase as Pregnancy Progresses

Legal abortion is among the safest procedures in medicine, and it is significantly safer than childbirth. Sam Rowlands, *Review: Misinformation on Abortion*, 16 Eur. J. Contraception & Reprod. Health Care 233, 234 (2011); Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215, 216 (2012). Indeed, legal abortions by all methods are thirty times less likely to cause death than childbirth, Rowlands, *supra*, at 234, and surgical abortion in the United States is seventy times less likely to cause death than childbirth. *Id.* at 235 tbl.1.

Medical abortion (*i.e.* abortion performed using medication only) is a common method of abortion early in pregnancy. It is approved by the FDA for use through ten weeks gestation. *Mifeprex (Mifepristone) Information*, U.S. Food & Drug Admin., http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111323.htm. Medical abortion is the preferred method for some women for a number of reasons, and an increasing percentage of women have chosen medical abortion in recent years. Nathalie Kapp et al., *Efficacy of Medical Abortion Prior to 6 Gestational Weeks: A Systematic Review*, 97 Contraception 90, 90 (2017) ("Medical abortion at less than 9 weeks of gestation accounted for 31% of all clinic-based abortions in 2014 in the US, as compared with 24% in 2011."); Tara C. Jatlaoui et

al., *Abortion Surveillance – United States, 2013*, Morbidity & Mortality Wkly. Rep.: Surveillance Summaries, Nov. 25, 2016, at 1, 8 ("[F]rom 2004 to 2013, use of early medical abortion increased 110% (from 10.6% of abortions to 22.3%).").

The FDA-approved regimen for medical abortion becomes somewhat less effective later in pregnancy, however, and medical abortion thus is generally not performed in the United States after ten weeks of gestation. *See* Am. Coll. of Obstetricians & Gynecologists, *Practice Bulletin No. 143: Medical Management of First-Trimester Abortion*, 123 Obstetrics & Gynecology 676, 677 (2014) ("Complete abortion rates are higher with earlier gestations; approximately 96-98% in gestations of up to 42 days, 91-95% in gestations from 43 days to 49 days, and less than 85% in gestations beyond 49 days."); David A. Grimes, *The Choice of Second Trimester Abortion Method: Evolution, Evidence and Ethics*, 16 Reprod. Health Matters 183, 184–85 (2008). As a result, some women who are delayed in obtaining an abortion because of tactics used to discourage abortions in some facilities covered by the FACT Act will be deprived of the option of having a medical abortion. *See* Grimes, *supra*, at 184. Among the most harmed are women for whom medical abortion may have been the most appropriate method, such as women who have uterine fibroids that make access to the fetus more difficult or infeasible. *See, e.g.*, Mitchell D. Creinin, *Medically Induced Abortion in a Woman with a Large Myomatous Uterus*, 175 Am. J. Obstetrics & Gynecology 1379, 1379 (1996).

Further, although the complication rate of both medical and surgical abortion is very low, it increases as gestational age increases. Justin Diedrich & Jody Steinauer, *Complications of Surgical Abortion*, 52 Clinical Obstetrics & Gynecology 205, 205, 206 (2009); Karasek et al., *supra*, at 65; Rebecca Allen & Alisa B. Goldberg, *Cervical Dilation Before First-Trimester Surgical Abortion (<14 Weeks' Gestation)*, 93 Contraception 277, 281 (2016); Christine Dehlendorf et al., *Disparities in Abortion Rates: A Public Health Approach*, 103 Am. J. Pub. Health 1772, 1776 (2013); Upadhyay et al., *Denial*, *supra* note 2, at 1687. Further, while the risks remain small, additional delay in obtaining an abortion later in pregnancy increases the risk of complications, including death, more than delay early in pregnancy. Diedrich & Steinauer, *supra*, at 205; Mary Gatter et al., *Efficacy and Safety of Medical Abortion Using Mifepristone and Buccal Misoprostol Through 63 Days*, 91 Contraception 269, 271-72 (2015). For example, the risk of major complications for surgical abortions in the first trimester is only 0.16%. Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175, 178 (2015). That risk more than doubles for abortions performed in the second trimester (albeit still very low at 0.41%). *Id.*; *see also* Allen & Goldberg, *supra*, at 277.

In addition to the risk of complication, the risk of death from legal abortion is extremely low and significantly lower than from childbirth. *See* Raymond & Grimes, *supra*, at 215-16 ("The risk of death associated with childbirth is approximately 14

times higher than that with abortion. . . . The mortality rate related to legal induced abortion . . . was 0.6 deaths per 100,000 abortions."). Nonetheless, this risk increases as gestational age increases. Suzanne Zane et al., *Abortion-Related Mortality in the United States: 1998–2010*, 126 Obstetrics & Gynecology 258, 263 (2015). Indeed, "[g]estational age at the time of the abortion remains the strongest risk factor for abortion-related mortality." *Id.* Significantly, the risk of mortality—as with complications—increases disproportionately with time. The mortality rate for abortions (*i.e.*, the number of abortion-related deaths per every 100,000 legal induced abortions) is 0.3 before 8 weeks, 0.5 at 9–13 weeks, 2.5 at 14–17 weeks, and 6.7 at or after 18 weeks. *Id.* at 262. (It must be noted, however, that even later in the second trimester, abortion remains much safer than carrying a pregnancy to term. *See* Marian F. MacDorman et al., *Recent Increases in the U.S. Maternal Mortality Rate: Disentangling Trends from Measurement Issues*, 128 Obstetrics & Gynecology 1, 1 (2016) (finding maternal mortality rate of 23.8 deaths per 100,000 live births in the 2014).)

From a public health standpoint, any risks that can be avoided by unnecessary delays should be avoided. In the context of legal abortion, although it is overall an extremely safe procedure, health risks increase when a woman's access to proper medical care is delayed. Thus, while it is essential to view the increasing risks of abortion associated with advancing gestational age relative to the

significantly greater risks of continuing a pregnancy, it is equally essential to minimize any unnecessary delay in a legal abortion.

C. Delay Makes It More Likely That Some Women Will Be Denied an Abortion

Timely access to medical care is critical to optimize health and to reduce health care costs. Delay in obtaining an abortion not only increases a woman's health risks but also makes the service sought either harder to obtain or, at some point, impossible to obtain.[5] As a matter of public health policy and legal policy, women should have access to available medical services without unnecessary obstacles. *See Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 874 (1992) (indicating that legislation cannot unduly burden a woman's access to abortion services); *Restricted Access to Abortion Violates Human Rights, Precludes Reproductive Justice, and Demands Public Health Intervention*, Am. Pub. Health Ass'n, http://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2016/01/04/11/24/restricted-access-to-abortion-violates-human-rights.

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[5] Although the majority of abortions in the United States take place during the first trimester of pregnancy, approximately 8.4% of abortions occur after 13 weeks of gestation. Jatlaoui et al., *supra*, at 1. Most women who had second trimester abortions, however, would have preferred to have had the procedure earlier. Upadhyay et al., *Denial*, *supra* note 2, at 1687; Valerie French et al., *Influence of Clinician Referral on Nebraska Women's Decision-to-Abortion Time*, 93 Contraception 236, 240 (2016).

First, abortions become more expensive as pregnancy advances, potentially limiting some women's ability to obtain an abortion. Upadhyay et al., *Denial, supra* note 2, at 1687 (showing that the cost of abortion at 20 weeks is roughly triple the cost of abortion at 10 weeks); *see also* Medoff, *supra* note 2, at 238.

Second, there are fewer trained abortion providers who perform abortions as pregnancy continues. "According to a national survey of abortion providers, 23% offer abortions after 20 weeks' gestation, and 11% do so at 24 weeks." Upadhyay et al., *Denial, supra* note 2, at 1687. Moreover, there is an overall dearth of abortion providers in the United States. *See ACOG Committee Opinion No. 613, supra*, at 1063 ("The number of facilities providing abortion in the United States decreased 38% from 1982 to 2000, and continues to decrease. More than one third of U.S. women live in the 89% of counties that lack an abortion care facility . . . ."). Thus, additional delay will force many women to travel long distances to obtain an abortion. In effect, this means that some women who are delayed from accessing abortion care earlier in their pregnancies will be precluded from obtaining an abortion at all.[6]

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[6] This outcome is most likely for women without access to transportation, those who must arrange for childcare, and those who must take time away from their jobs. *See* Upadhyay, *Denial, supra* note 2, at 1687.

Indeed, abortion does not remain an option for women for the entire duration of pregnancy, as states have greater leeway to restrict abortion after viability. *See Casey*, 505 U.S. at 846. Thus, for some women, delay in obtaining abortion will result in the loss of that option altogether even if it is in the best interests of the woman's health.

Women should be able to obtain medical services as appropriate for their circumstances. Medical options should not be limited by avoidable delay.

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Notifying patients that comprehensive health care services are available to them significantly increases the likelihood that they will seek and receive those services and thereby reduces the risks associated with delayed or inadequate health care. The converse is also true: depriving patients of information regarding services that are critical to their health prevents or delays their access to those services. And even those patients who are aware that services exist but incorrectly believe that they cannot afford those services are unlikely to seek or obtain them. Accordingly, providing notice to women as early as possible that free or low-cost prenatal care, family planning and abortion services are available to them reduces the significant health-related harms detailed above. The FACT Act facilitates women's awareness of, and thus access to, this care.

II. Women Must Be Informed Whether Or Not Health Care They Receive Is Provided By Or Under The Supervision Of A Licensed Medical Provider

A core principle of the practice of medicine is the duty of a licensed medical provider to competently provide medical treatment. Am. Med. Ass'n, *AMA Code of Medical Ethics* 1 (2001), *available at* https://www.ama-assn.org/sites/default/files/media-browser/principles-of-medical-ethics.pdf ("A physician shall be dedicated to providing **competent** medical care . . . ."); Am. Nurses Ass'n, *Code of Ethics for Nurses with Interpretive Statements* §5.5, at 19 (2015), *available at* http://nursingworld.org/DocumentVault/Ethics-1/Code-of-Ethics-for-Nurses.html ("Nurses must maintain competence and strive for excellence in their nursing practice, whatever the role or setting."). Unlicensed persons providing medical care without adequate competency run the risk of harming patients and violating the law through their unlicensed practice of medicine. *See* Am. Coll. of Obstetricians & Gynecologists, *Code of Professional Ethics* 3 (2011) [hereinafter *ACOG Code of Professional Ethics*], *available at* https://www.acog.org/-/media/Departments/National-Officer-Nominations-Process/ACOGcode.pdf?dmc=1&ts=20180224T2126120836 ("The obstetrician-gynecologist should recognize the boundaries of his or her particular competencies and expertise and must provide only those services and use only those techniques for which he or she is qualified by education, training, and experience."); Cal. Bus. & Prof. Code §§ 2052, 2053.5.

Patients can neither fully consent nor make fully informed decisions about their health care if they are not meaningfully informed about the care they are receiving or the qualifications and expertise of the individual who will be providing the care. *Informed Consent: Code of Medical Ethics Opinion 2.1.1*, Am. Med. Ass'n, https://www.ama-assn.org/delivering-care/informed-consent ("Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care."); *Withholding Information from Patients: Code of Medical Ethics Opinion 2.1.3*, Am. Med. Ass'n, https://www.ama-assn.org/delivering-care/withholding-information-patients ("Truthful and open communication between physician and patient is essential for trust in the relationship and for respect for autonomy."); Am. Nurses Ass'n, *supra*, §2.1, at 5 ("Honest discussions about available resources, treatment options, and capacity for self-care are essential.").

In addition, the health care professional and the patient share responsibility for the patient's health, and the well-being of the patient depends upon their collaborative efforts. *Patient Rights: Code of Medical Ethics Opinion 1.1.3*, Am. Med. Ass'n, https://www.ama-assn.org/delivering-care/patient-rights; *see also* Am. Coll. of Obstetricians & Gynecologists, *Committee Opinion No. 578: Elective Surgery and Patient Choice*, 122 Obstetrics & Gynecology 1134, 1135 (2013) ("The goal should be decisions reached in partnership between patient and physician."); Am. Nurses Ass'n, *supra*, § 1.2, at 1 ("Nurses establish relationships of trust and provide nursing services according to need . . . ."). Within the

patient–provider relationship, the provider's respect for the patient's autonomy is fundamental. *ACOG Code of Professional Ethics*, *supra*, at 1; Am. Coll. of Obstetricians & Gynecologists, *Committee Opinion No. 390: Ethical Decision Making in Obstetrics and Gynecology*, 110 Obstetrics & Gynecology 1479, 1481 (2007); *cf. Doe v. Bolton*, 410 U.S. 179, 197 (1973) (recognizing a "woman's right to receive medical care in accordance with her licensed physician's best judgment"); *Cruzan ex rel. Cruzan v. Dir., Missouri Dep't of Health*, 497 U.S. 261, 289 (1990) (O'Connor, J., concurring) (recognizing a "patient's liberty, dignity, and freedom to determine the course of her own treatment"). Deciding on the best form of pregnancy-related health care for any given patient should take place within this established patient-provider relationship. This is particularly true given the highly personal nature of the reproductive health and family planning services at issue.

Patients must be aware when what may ***appear*** to be medical care provided by a licensed medical professional and at a licensed facility is in fact being provided by an unlicensed provider or clinic that does not receive important quality oversight from the relevant licensing board within the California Department of Consumer Affairs or the California Department of Public Health. That awareness will allow them to make a better-informed decision whether to seek care elsewhere and whether to have a procedure done at all.

One such example relates to the provision of ultrasounds, procedures that use high-frequency sound waves to scan a woman's abdomen and pelvic

cavity to create a picture of the fetus. Ultrasounds are commonly used by health care professionals during a woman's pregnancy. *Ultrasound Imaging*, U.S. Food & Drug Admin., https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm115357.htm. Thus, a woman may reasonably assume that if she is offered an ultrasound, the ultrasound is medically necessary. She also may reasonably assume, unless informed otherwise, that the ultrasound is being performed by or at the direction of a competent and licensed medical provider. She further may assume that she will be informed of the need for follow-up evidence-based medical care if the ultrasound reveals any abnormalities or issues. All of these assumptions may be incorrect, however.[7]

Licensed medical providers are the only ones in a position to provide pregnant women with the information they need to decide whether and when an ultrasound should be performed. They also are best able to interpret the ultrasound's results in a competent manner. *ACOG Practice Bulletin No. 175*, *supra* note 7, at e245-46 ("[U]ltrasonography should

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[7] Some ultrasounds are provided by facilities offering "keepsake" ultrasounds, which provide women with images of the developing fetus for non-medical reasons. Other ultrasounds are provided by facilities that seek to convince women not to have an abortion. The use of ultrasonography without a medical indication is inappropriate and contrary to responsible medical practice. *See* Am. Coll. of Obstetricians & Gynecologists, *Practice Bulletin No. 175: Ultrasound in Pregnancy*, 128 Obstetrics & Gynecology e245, e245-46 (2016) [hereinafter *ACOG Practice Bulletin 175*].

be performed only when there is a valid medical indication and, in all cases, the lowest possible ultrasound exposure settings that obtain adequate image quality and gain the necessary diagnostic information should be used, following the as-low-as-reasonably-achievable (ALARA) principle.").

When non-medically necessary ultrasounds are administered, "patients may not receive the necessary support, information, and follow-up" for any abnormalities. *Id.* at e247. Moreover, "nonmedical ultrasonography may falsely reassure pregnant women who may incorrectly believe that the ultrasound imaging is diagnostic." *Id.* Indeed, non-medical ultrasounds may be incorrectly viewed as a substitute for needed medical care. As the International Society of Ultrasound in Obstetrics and Gynecology ("ISUOG") has recognized, even if "sessions are described as 'non-medical,'... 'customers' often assume they have undergone a medical scan and may therefore forfeit a regular, scheduled medical scan." J. Abramowicz et al., *ISUOG Statement on the Non-Medical Use of Ultrasound, 2009*, 33 Ultrasound in Obstetrics & Gynecology 617, 617 (2009). Further, if an unlicensed medical provider performs an ultrasound and provides inaccurate results (whether intentionally or due to lack of training), health concerns such as fetal abnormalities and ectopic pregnancies can be overlooked and left untreated. Due to these concerns, "[t]he position of the [American Institute of Ultrasound in Medicine] is that only qualified individuals should perform sonograms, and that they must be able to recognize

important conditions, such as birth defects, and, conversely, artifacts that may mimic fetal pathology." *Id.* at 619.[8]

The risks associated with women incorrectly believing that a service is both medically indicated and being performed in a competent manner, including recommendations for follow-up medical care if necessary, are reduced when the women are

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[8] Indeed, a number of prominent regulatory and health organizations have advised women not to get non-medical ultrasounds. *See, e.g.*, *Avoid Fetal "Keepsake" Images*, U.S. Food & Drug Admin., https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm095508.htm ("[T]he FDA strongly discourages [ultrasound] use for creating fetal keepsake images and videos."); Stanley B. Barnett et al., *International Recommendations and Guidelines for the Safe Use of Diagnostic Ultrasound in Medicine*, 26 Ultrasound in Med. & Biol. 358, 364 (2000); Press Release, Am. Inst. of Ultrasound in Med., The AIUM Reaffirms its Opposition to Entertainment Ultrasound (Apr. 2, 2004), *available at* http://www.aium.org/press/viewRelease.aspx?id=66 ("The use of either two-dimensional (2-D) or three-dimensional (3-D) ultrasound to only view the fetus, obtain a picture of the fetus or determine the fetal gender without a medical indication is inappropriate and contrary to responsible medical practice."); Abramowicz et al., *supra*, at 617 ("ISUOG disapproves of the use of ultrasound for the sole purpose of providing souvenir images of the fetus."); *Non-Diagnostic Use of Ultrasound for Entertainment Purposes in the Obstetrical Setting*, Soc'y of Diagnostic Med. Sonography (June 8, 2011), https://sdmspositionstatements.wordpress.com/2011/06/08/6/ ("The use of two-dimensional (2D), three-dimensional (3D) or four-dimensional (4D) ultrasound to only view the fetus, obtain a picture of the fetus or determine the fetal gender without a medical indication is inappropriate and, in the view of the Society of Diagnostic Medical Sonography (SDMS), contrary to responsible medical practice.").

informed that the facility does not have a licensed medical provider on staff. The FACT Act, which requires an unlicensed facility administering pregnancy-related services to provide notice that the facility is unlicensed and that it has no licensed medical provider on staff, will enable pregnant women to make informed decisions about their health and the health of the developing fetus.

CONCLUSION

Amici respectfully request that the Court affirm the decision below.

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Respectfully submitted,

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